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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/727,084	10/08/96	PULST S	P07-37217

HM22/0614
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EXAMINER	
ALLEN, M	
ART UNIT	**PAPER NUMBER**
1645	29
DATE MAILED:	06/14/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/727,084	Applicant(s) Pulst
	Examiner Marianne P. Allen	Group Art Unit 1645

☒ Responsive to communication(s) filed on *5/26/98 and 10/23/98*.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-5, 7-13, 40, 43, 49, and 52-54* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-5, 7-13, 40, 43, 49, and 52-54* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *21, 28*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Claims 6, 14-39, 41-42, 44-48, and 50-51 have been cancelled. Claims 1-5, 7-13, 40, 43, 49, and 52-54 are under consideration by the examiner.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments filed 5/26/98 and 10/23/98 have been fully considered but they are not persuasive.

The sequence listing and corresponding CRF submitted 10/23/98 are noted.

The art rejections have been withdrawn with respect to some of the claims in view of the new matter rejections set forth below; however, applicant is advised that the art could be reapplied if the new matter rejections are overcome.

The oath or declaration remains defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath remains defective for reasons of record. Although applicant indicates in the response that a new oath was attached, it does not appear to have been attached and is not present in the application.

Claims 1-5, 7-9, 12, 40, 49, and 52-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 has been amended to be directed to nucleic acids encoding mammalian SCA2 polypeptides which comprise SEQ ID NO: 6, SEQ ID NO: 19, and a CAG repeat sequence. Introduction of SEQ ID NO: 19 into the specification and claims is deemed to be new matter. Applicant points to Figure 6A for basis; however, this is not agreed with. This figure provides basis for the primer SCA2-B which is complementary to this sequence but not basis for the sequence itself. (See page 43.) Nowhere in the specification is a mammalian SCA2 nucleic acid sequence identified as comprising these three elements as the defining features. Particular elements of the sequence of Figure 6 cannot be construed as basis for a generic claim. The subject matter of claim 52 is new matter for the same reasons. Nowhere in the specification is a contemplated DNA fragment identified as comprising these two elements as the defining features to support a generic claim.

In addition, the hybridization conditions set forth in claim 5 are disclosed with reference to a particular sequence and experiment (see page 45) and not the particularly recited sequences of the claims. The conditions in the example cannot be construed as basis for a generic claim.

Claims 12 and 40 have been amended to recite "at least two oligonucleotides" to amplify a CAG repeat sequence. The disclosure of kits on page 22 does not recite at least two oligonucleotides, it is directed to at least one. Examples using at least two oligonucleotides cannot be construed as basis for a generic claim.

Claim 49 is stated to have basis in claim 46. First of all, claim 46 is not an originally filed claim. Secondly, claim 46 was dependent upon claim 44 which required at least about 35 CAG repeats. Applicant is requested to point to basis in the specification by page and line number for this generic concept.

Should these new matter rejections be overcome, the claims would be subject to a rejection under 35 USC 112, first paragraph, similar to that set forth in the prior Office action.

As stated in the prior Office action, with the exception of SEQ ID NO: 2 and degenerate sequences which encode SEQ ID NO: 3, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides. The partial sequences of SEQ ID NOS: 1, 4, and 5 are not of sufficient size or similarity to permit one to visualize the complete sequence for the SCA2 polypeptides nor nucleic acid sequences encoding them. It is noted that the specification itself indicates that the mouse and the human SCA2 sequences have only a short region of high homology and that the gene product ataxin-2 has significant similarity to a domain of an unrelated protein, A2RP. The specification identifies no known biological activity for the SCA2 polypeptide or ataxin-2 (it is unclear if these terms are interchangeable) and provides no assays for determining such. As the definition on page 15 for SCA2 polypeptide requires biological activity, the alternate forms included within the SCA2 definition are not enabled.

Claims 4-5 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-5 are confusing in reciting "obtained from the isolated nucleic acid sequence." It appears that this is intended to limit the claim to fragments of the particular nucleic acid sequences of claim 2 rather than additional related sequences that would hybridize but would contain other nucleotides (see claim 5) or any sequence that would encode the recited 10 contiguous amino acids but might contain other additional amino acid sequences (see claim 4), but it is unclear.

Claim 40 is confusing in reciting "at least two single strand DNA primers." No relationship is set forth for the two elements such as forming a composition or a kit. It's not clear if this is a statutory claim.

Claim 10 is rejected under 35 U.S.C. 102(a) as being anticipated by EST Accession No. W39162 from the WashU-Merck EST Project.

This EST has 417 nucleotides of which 393 match SEQ ID NO: 2. It encodes the last 9 amino acids of SEQ ID NO: 3. The EST meets all of the structural requirements of the claim.

Contrary to applicant's assertion, applicant is not entitled to the provisional application filing date. The full scope of the invention as claimed is not disclosed nor contemplated in the provisional application.

Claim 10-11 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Orr et al. (Nature Genetics, 1993).

Orr et al. discloses a 400 bp fragment with CAG trinucleotide repeats. $(GCT)_7$ PCR primers were used as a CAG repeat probe. This primer could also be labelled with P^{32}. (See page 225.) This primer would hybridize to the recited sequences. The functional language "to detect a CAG repeat sequence in an SCA2 gene..." is given no patentable weight in the product claim of claim 43. With respect to claim 43, the primer would have been made and stored in some sort of container thereby meeting the limitation of "packaging material."

Claims 10-11 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawaguchi et al.

Kawaguchi et al. discloses a probe for detecting CAG trinucleotide repeats. The $GATCT(CTG)_{13}G$ was used as a CAG repeat probe. This probe was labelled with P^{32}. (See page 226.) This primer would hybridize to the recited sequences. The functional language "to detect a CAG repeat sequence in an SCA2 gene..." is given no patentable weight in the product claim of claim 43. With respect to claim 43, the primer would have been made and stored in some sort of container thereby meeting the limitation of "packaging material."

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 9:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703) 308-3995. Official FAX communications may be directed to either (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER
~~GROUP 1800~~
AU 1645